



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/419,517	10/18/99	KAESEMEYER	W 97-092-US-C2

FREDERICK H COLER
REED SMITH SHAW & MCCLAY
P O BOX 488
PITTSBURGH PA 15230

HM12/1204

EXAMINER

KIM, J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED:

12/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/419,517

Applicant(s)

KAESEMEYER, WAYNE H.

Examiner

Jennifer M Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12, 13 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12, 13 and 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

09/419,517

Art Unit: 1617

DETAILED ACTION

Claims 1-6, 12-13, and 16-26 are presented for examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-2, 5, 12-13, 16, 18, 20-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Liao et al. (U.S. Patent No. 6,147,109).

Liao et al. at the abstract, column 9, lines 10-27 (particularly lines 26 and 27), column 10, lines 19-27 (particularly line 27), and column 11, line 59 through column 12, line 5, teach applicants method and a composition comprising treating a disease condition in a subject comprising administering a mixture of L-arginine and Hmg-CoA reductase

09/419,517

Art Unit: 1617

(atorvastatin or cerivastatin) by using various routes set forth in claim 2.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-4, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao et al. (U.S. Patent No. 6,147,109).

Liao et al. teach at the abstract, column 5, column 7, lines 63 through column 8, line 6 (particularly line 5), column 10, lines 5-14, teach that Applicants' therapeutic mixture (see above rejection) can be used to treat various diseases including heart failure, renal disease, and including subjects with coronary heart disease, hypertension, cerebrovascular disease or peripheral vascular disease.

09/419,517

Art Unit: 1617

The difference between above reference and Applicant's invention is absence of the step of obtaining periodic indicators of vasorelaxation as set forth in claim 19, and the excess amount of L-arginine to Hmg-CoA reductase inhibitor as set forth in claim 17.

However, obtaining periodic indicators of vasorelaxation to subject who is getting an agent which increase blood flow and the amounts of active agents to be used are all deemed obvious since they are all within the knowledge of the skilled pharmacologist.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer

Application/Control Number:

Page 5

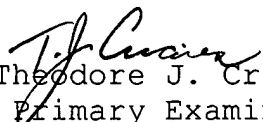
09/419,517

Art Unit: 1617

Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
November 22, 2000